K110289

AUG 30 2011

3. Attachment I: 510(K) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Summary Date:	May 6, 2011
Submitter's information:	Zhai Ying Chuan General Manager Xian Friendship Medical Electronics Co., Ltd. Gao Xin 1st Road, Hi-Tech Development Zone, Xi'an, Shaanxi, China, 710075 Phone: (86) -29-88225200 Fax: (86)- 29-88236285 georgezhai2616@163.com
Trade Name:	Friendship Pre-gelled Ag/AgCl Surface Electrodes
Common Name:	Disposable Ag/AgCl Pre-gelled Surface Electrodes
Classification Name:	21 CFR section 882.1320. Cutaneous Electrode.
Product Code:	GXY
Predicate Devices:	Sunspot Pre-gelled Surface Electrodes (K062198) manufactured by Axon Systems, Inc. Rthymlink International Cutaneous Pad Electrodes (K052188) manufactured by Rhythmlink International, LLC.

10.1 Device Description:

Friendship's Pre-gelled Ag/AgCl Surface Electrodes are disposable (for "single Use Only"). Used to detect electrophysiological signals or provide electrical stimulation subcutaneously. The electrodes are the interface medium between the diagnostic or monitoring equipment and the patient. The surface electrodes is comprised of top woven layer, carbon layer, Ag/AgCl layer and hydrogel layer on one end electrically connected to lead wire and a touch-proof connector on the other end. The surface electrodes are placed cutaneously by a licensed physician or technologist under the supervision of a

were already verified and validated.

10.6 Brief discussion of the clinical tests submitted:

Clinical studies were not deemed necessary regarding the surface electrodes due to their similarity in materials, design and function to those "predicate device". The device was evaluated by health care professionals during a simulated use test and was found to be acceptable for its intended use.

10.7 Biocompatibility testing

The contact material Katecho hydrogel is of known biocompatibility. Those materials were already tested for material safety and biocompatibility by the Katecho Inc.:

- Cytotoxicity study – ISO 10993-5
- Skin irritation study – ISO 10993-10
- Skin sensitization study – ISO 10993-10

10.8 Performance testing

The electrical performance of the Surface Electrode has been tested and meet the voluntary standard requirements under ANSI/AAMI EC12/2000 in compliance with IEC60601-1.

10.9 Conclusions:

Xian Friendship Medical Electronics Co., Ltd.'s Surface Electrodes are substantially equivalent to the predicate devices. Xian Friendship Medical Electronics Co., Ltd. manufactures the Surface Electrodes for Axon Systems, Inc. There are no new questions of safety or effectiveness raised or evident.

Box	48 electrodes/box	48 electrodes/box

Specification	**Equivalent Device**	**Predicate Device 1 B**
Manufacturer	Xian Friendship Medical Electronics Co., Ltd.	Axon Systems, Inc
Part number or 510(k)	Part Number: SEAg-Cu-S	FDA 510(K): K062198
Part number	SEAg-Cu-S-1500/2.0x2.7	DSE2115
Part	Pre-gelled Surface Electrode	Pre-gelled Surface Electrode
Classification	II	II
Description	Single and twisted pair, Pre-gelled Surface Electrode	Single and twisted pair, Pre-gelled Surface Electrode
Dimensions	27 mm x 20 mm , various size	27 mm x 20 mm , various size
Electrode shapes	Round/oval design , various	Duck-foot design , various
Sensor Material	Ag/AgCl	Ag/AgCl
Hydrogel type	Solid gel Katecho KM10E.	Solid gel Katecho KM 10E
Connector	DIN 42802	DIN 42802
Lead Length	Various: 1.5M, 2.0M, 2.5M, 3.0M (other lengths may be added)	Various: 1.5M, 2.0M, 2.5M, 3.0M (other lengths may be added)
Lead wire color	Multiple colors	Multiple colors
Labeled as	Single use, disposable	Single use, disposable
Indications for use	Stimulation and recording	Stimulation and recording
Pouch	Aluminum polyester	Aluminum polyester
Standard Electrode Type	AAMI EC12 2000	AAMI EC12 2000
Stated potential adverse reactions	Skin irritation	Skin irritation

Pouch	Aluminum polyester	Aluminum polyester
Standard Electrode Type	AAMI EC12 2000	AAMI EC12 2000
Stated potential adverse reactions	Skin irritation	Skin irritation
Packaging	1 electrode/pouch	1 electrode/pouch
Box	24 electrodes/box	24 electrodes/box

Specification	**Equivalent Device**	**Predicate Device 1 D**
Manufacturer	Xian Friendship Medical Electronics Co., Ltd.	Axon Systems, Inc
Part number or 510(k)	Part Number: SEAg-Cu-S	FDA 510(K): K062198
Part number	SEAg-C 3.0	DSE3003
Part	Pre-gelled Surface Electrode	Pre-gelled Surface Electrode
Classification	II	II
Description	Single and twisted pair, Pre-gelled Surface Electrode	Single and twisted pair, Pre-gelled Surface Electrode
Dimensions	30mm in diameter, round size	50 mm x50 mm x 60 mm , triangle
Electrode shapes	Round/oval design , various	Triangle design , various
Sensor Material	Ag/AgCl	Ag/AgCl
Hydrogel type	Solid gel Katecho KM10E.	Solid gel Katecho KM 10E
Connector	Metal snap	Metal snap
Labeled as	Single use, disposable	Single use, disposable
Indications for use	Stimulation and recording	Stimulation and recording
Pouch	Aluminum polyester	Aluminum polyester
Standard Electrode Type	AAMI EC12 2000	AAMI EC12 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Xian Friendship Medical Electronics Co., Ltd.
c/o Zhai Ying Chuan
General Manager
No. 9 Gao Xin 1st Road, Hi-Tech Development Zone
Xi'an Shaanxi 710075 China

AUG 30 2011

Re: K110289
Trade/Device Name: Friendship Medical Disposable Pre-gelled Ag/AgCl Surface Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: Undated
Received: July 21, 2011

Dear Mr. Zhai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110289

Device Name: Disposable Pre-gelled Ag/AgCl Surface Electrode

Indications For Use:

Disposable Pre-gelled Ag/AgCl Surface Electrodes are intended for recording/stimulation

and monitoring of the Electromygraphy (EMG), Electroencephalograph(EEG)

and Evoked Potential(EP) signals.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110289